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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,825	05/23/2001	Robert E. Krall	PROV1110-3	9432

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GARY CARY WARE & FRIENDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1600
SAN DIEGO, CA 92121-2189

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/09/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/863,825

Applicant(s)

KRALL ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-23, 27-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alkyl cyanoacrylates, does not reasonably provide enablement for polymerizable organic monomers in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant discloses only cyanoacrylates as examples of polymerizable organic monomers. Any such compounds must both be compatible with the cyanoacrylate and biocompatible with a mammalian body. As such, a skilled artisan would be required to do undue experimentation to determine what compounds would be suitable as polymerizable organic monomers and would be biocompatible with the mammalian body.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Pat. 5,695,480) in view of Tseng et al., Woodward, Clark et al. (US Pat. 5,981,621), Hoffman (US Pat. 4,359,454), Krall (US Pat. 4,713,235), Almen et al., EP 0 747 069 and Leung et al. (US Pat. 5,328,687).

Evans et al. teach a compositions and methods for embolizing blood vessels using microballoon catheters and treating arteriovenous malformations comprising a biocompatible prepolymer, such as a cyanoacrylate, which is preferably non-inflammatory, a contrast agent, such as gold, and optionally a biocompatible solvent (Column 1, lines 65-68, Column 2, lines 1-6, Column 3, lines 60-68, Column 4, lines 1-13, Column 5, lines 63-68, Column 6, lines 1-6, 26-36).

Tseng et al. teach that 2-cyanoacrylates are widely used in surgical fields as hemostatic agents and tissues adhesives, and have been used in the therapeutic embolization of arteriovenous malformation (pg. 65). It is taught that the physicochemical properties of 2-cyanoacrylates can be improved to obtain higher reliability by mixing with a contrast medium as they are not radiopaque, having appropriate viscosity and set time in blood, and low bonding strength so that the microcatheter is removed easily (Pgs. 65,66). It is taught that homologues of ethyl 2-cyanoacrylate and isobutyl 2-cyanoacrylate having a longer ester side group generate more flexible polymers than homologues with shorter ones (Pg. 66). Lipiodol ultra-fluide is taught as a suitable radiopaque material (Pg. 66).

Woodward teaches that hexyl 2-cyanoacrylate as compared to ethyl, butyl and octyl 2-cyanoacrylates stimulated only a transient inflammatory response (Abstract).

Clark et al. teach that plasticizers, such as isopropyl myristate, impart flexibility to the polymerized cyanoacrylate monomer (Column 6, lines 21-30). It is taught that anionic

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stabilizing agents such as phosphoric acid, hydroquinone, and p-methoxyphenol, and mixtures thereof, inhibit polymerization (Column 6, lines 34-51, Column 18, Claim 17). It is taught that the stabilizing agent is present in the range of 20-200 ppm (Column 18, Claim 18).

Krall teaches method of sterilizing females using cyanoacrylates in the fallopian tubes (Column 5, lines 45-58).

Almen et al. teach that alkyl cyanoacrylates present a reasonable compromise between adhesive capabilities and toxicity and that the chemistry and use of the tissue adhesives have been extensively reviewed, including their use with magnetic powder to be guided and confined to the area of treatment (Pg. 348).

EP 0 747 069 teaches a medical device such as a stent or heart valve which is employed with polymer systems, such as cyanoacrylates (Column 3, lines 20-58, column 7, lines 56-58, column 8, lines 1-21, column 14, lines 19-39).

Leung et al. teach that alpha cyanacrylates are useful as tissue adhesives, sealants for preventing bleeding, covering wounds, delivery of therapeutic or other bioactive agents, apposing surgically incised or injured tissue and as implants (Column 3, lines 10-21, column 8, lines 21-68, column 9).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of mixtures of alkyl cyanoacrylates with a second component which includes an oligomer of alkyl cyanoacrylate, a plasticizer and opacificant agent. However, the same is amply suggested by the prior art as compositions and methods comprising alkyl cyanoacrylates, plasticizers and opacificant agents and methods for their use are known in the art. As such, it would have been well within the skill of and one of ordinary skill in the art

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would have been motivated to use alkyl cyanocrylates because of their proven effectiveness and safety.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Note that the above is not intended to apply to subject matter patented in U.S. Patents Nos. 6,037,366 (Krall et al.) and 4,713,235 (Krall) and applied herein below as the prior art does not provide the requisite disclosure, suggestion, or motivation to utilize 2-hexyl cyanoacrylate in combination with all of the other specific compounds as set forth in claims 1-5 of the former and the combination of the ester of 2-cyanoacrylic acid in combination with triiodophenol, iodoform or tetraiodoethylene having the claimed amounts of iodine as set forth in Claims 1-15 of the latter.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,037,366 (Krall et al.) in view of Evans et al., Krall, Almen et al., EP 0 747 069 and Leung et al..

Krall et al. claim a composition and method for the creating therapeutic vascular occlusions comprising mixture of a Part 1 comprising 2-hexyl cyanoacrylate, hydroquinone (100 PPM), p-methoxyphenol (100 PPM) and phosphoric acid (250 PPM), and a Part 2 comprising gold metal powder, ethyl myristate and a sterilized polymer of 2-hexyl cyanoacrylate in a weak aqueous bicarbonate solution (Column 4, lines 20-32, 38- 50, Claims 1, 2, 5).

Evans et al., Krall, Almen et al., EP 0 747 069 and Leung et al. are cited here for the same reasons as set forth above, and the discussion there is incorporated herein to avoid repetition.

The difference between the present invention and the claims in Krall et al. is that Krall et al. does not expressly claim methods in which a mixtures of alkyl cyanoacrylates are used. However, the prior art amply suggests the same as it is known in the art to alkyl cyanoacrylates for the claimed methods. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use alkyl cyanoacrylates because of their proven effectiveness and safety.

Therefore, the claimed invention, as a whole, would have been an obvious variation of U.S. Pat. No. 6,037,366 (Krall et al.), to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending

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Applications 09/823,775, 09/241,368, 09/497,075 and 09/577115, each in view of Evans et al., Krall, Almen et al., EP 0 747 069 and Leung et al..

The copending Applications claim various methods of using alkyl cyanoacrylates and/or 2-hexyl cyanoacrylate similar to that claimed in the present invention.

Evans et al., Krall, Almen et al., EP 0 747 069 and Leung et al.. are cited herein for the same reasons as above and are incorporated herein to avoid repetition.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose use of mixtures of alkyl cyanoacrylates, for sterilization of females, implantation of medical devices and/or the use of magnetized particles to direct the same to the desired site. However, the prior art amply suggests the same as it is known in the art to use alkyl cyanoacrylates for the claimed methods. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use alkyl cyanocrylates because of their proven effectiveness and safety.

Therefore, the claimed invention, as a whole, would have been an obvious variation of the claims of said copending applications, to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

This is a provisional obviousness-type double patenting rejection.

Conclusion

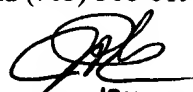
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

August 30, 2002



JOHN PAK
PRIMARY EXAMINER
GROUP 1700